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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,199	04/15/2004	Itzhak Kronzon	50129/00202	9818
30636 7590 09/25/2007 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			EXAMINER FLORY, CHRISTOPHER A	
			ART UNIT 3762	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,199

Applicant(s)

KRONZON, ITZHAK

Examiner

Christopher A. Flory

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007 and 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 July 2007 has been entered.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 7, 8, 10, 12-15 and 17-26 are rejected under 35 U.S.C. 102(e) as anticipated by Friedman (US Patent Publication 2003/0097167, hereinafter referred to

as Friedman'167) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friedman'167 in view of Shadduck (US 7,008,419, hereinafter Shadduck'419), or in view of Atlee, III (US 6,855,116, hereinafter Atlee'116), or in view of Melnikoff et al. (US 6,266,549, hereinafter Melnikoff'549) or in view of Van Venrooij et al. (US 7,212,867, hereinafter Venrooij'867).

Regarding claims 1-5, 10, 14 and 19, Friedman'167 discloses a medical apparatus used to treat cardiac arrhythmia comprising a flexible probe for accessing a patient's esophagus via the mouth with a proximal end which remains outside the patient and a distal end within the esophagus (TITLE; ABSTRACT; paragraphs [7], [10] and [32]); an echocardiography transducer coupled to the distal end at a predetermined location within the esophagus relative to the heart to perform transesophageal echocardiography (Fig. 1 TEE probe 3; paragraphs [6], [10] and [32]); and a plurality of electrodes spaced along a longitudinal axis of the probe included in the sheath (Fig. 2, electrodes 26; Fig. 3, leads 1-8) each coupled to a wire lead extending along the probe to a power source (paragraphs [9], [28] and [29]) for delivering a cardioversion or defibrillation current via the esophagus (paragraphs [15]-[17] and [36]-[38]).

Regarding claims 24 and 25, and further regarding claims 1, 14 and 20, Friedman'167 clearly shows in Figure 5 that the electrode assembly is C-shaped and non-annular. Alternatively, it is noted that the electrical contacts within the sheath are functional as electrodes in an operative position themselves, and clearly define a non-annular shape with a length no more than half of the circumference of the probe, which also means an opening of at least 110 degrees. Still further in the alternative,

Venrooij'867 describes non-annular C-shaped electrodes for directional stimulation and recording to improve localization of signals (title; abstract; column 15, line 39; Figures 3, 4, 6, 18). Shadduck'419 teaches non-annular electrodes (Figs. 5A-F) to be applied to the lower esophageal sphincter to induce injury healing response (abstract; column 9, lines 6-56). Atlee'116 shows an esophageal probe with C-shaped non-annular electrodes for providing cardiac pacing and oximetry (title; abstract; Figure 10 and related paragraphs). Melnikoff'549 teaches non-annular electrodes that are configured to be placed in the esophagus to generate or receive electrical signals indicative of the cardiac functions of the patient (abstract; Figs. 6, 11, 15, 17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Friedman'167 with the non-annular electrodes as taught by any one of these references to provide Friedman'167 with the respective advantages described in this paragraph as taught by Venrooij'867, Shadduck'419, Atlee'116 and Melnikoff'549.

Further regarding claims 24 and 25, given the interpretation of Friedman'167 that the electrical contacts within the sheath are functional electrodes, Friedman'167 clearly shows electrodes with a length no more than half of the circumference of the probe and an opening of at least 110 degrees. Alternatively, regarding the non-annular electrode ring shown in Fig. 5, although it is not expressly disclosed that the length be no more than half the circumference, it would have been obvious to one having ordinary skill in the art at the time of the invention to construct the electrode with such a length or angle of opening since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105

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USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode as taught by Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Friedman'167. Still further in the alternative, each of Venrooij'867, Shadduck'419, Atlee'116 and Melnikoff'549 clearly shows a non-annular electrode with a circumferential length no more than half that of the circumference of the probe, and with an opening of at least 110 degrees. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Friedman'167 with the electrodes as shown in these references, because Applicant has not disclosed that a length of less than half the circumference or an opening angle of at least 110 degrees provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrodes as disclosed in Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application.

Therefore, it would have been an obvious matter of design choice to modify the system of Friedman'167 to obtain the invention as specified in the claim(s).

Regarding claims 7, 17, 18 and 26, and further regarding claims 1 and 14, Friedman'167 discloses the electrodes mounted on or within a flexible sheath which is sized to be received over a distal portion of the probe and fixed thereon at a predetermined location relative to the echocardiography transducer (paragraphs [6], [7], [10]-[12] and [32]), the sheath being made of a biocompatible material (paragraph [32] discloses a sheath made of silicone) wherein the sheath/electrode is selectively mountable on and removable from the scope portion (paragraphs [11], [12] and [32]). It is noted that the electrical contacts within the sheath are functional as electrodes in an operative position themselves, and also that the act of clamping the electrode rings to the sheath can be reasonably interpreted to mean a sheath including an electrode.

Regarding claim 8, Friedman'167 discloses that the sheath can also be permanently bonded to the probe (paragraphs [34] and [35]).

Regarding claims 12 and 13, Friedman'167 discloses the electrode having a length of 7-10mm along an axial direction of the probe and being separated from a second electrode by a distance of 5-8mm (Fig. 3).

Regarding claim 15, Friedman'167 discloses an electrode assembly that is one of a single use assembly and a multiple use assembly, in that a single use assembly is defined identically to a removable and selectively mountable assembly, and a multiple use assembly is synonymous with a permanently bonded assembly as discussed with regards to claim 6, 8 and 9.

Regarding claim 20, Friedman'167 discloses a method of treating a heart of a patient comprising the steps of inserting a flexible echocardiography probe into the patient's esophagus, performing an echocardiography to analyze the condition of the heart, and applying electric current to the at least one cardioversion electrode to supply a current to the heart (paragraphs [13]-[17]).

Regarding claim 21, Friedman'167 discloses performing an additional echocardiography immediately after the cardioversion using the echocardiography transducer (paragraph [18]).

Regarding claims 22 and 23, Friedman'167 discloses coupling the electrode sheath to the probe prior to inserting the device into the esophagus and disposing of the sheath after completing the procedure (paragraphs [6], [7], [10], [11], [12], [32] and [33]).

5. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167, or in the alternative is unpatentable over Friedman'167 in view of Shadduck'419.

Regarding claim 11, Friedman'167 discloses the invention substantially as claimed but does not expressly disclose that the electrode is formed of a titanium foil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method as taught by Friedman'167 with a titanium foil electrode, since it is well known in the art that titanium is a good material for electrode construction due to its relatively low cost, durability, biocompatibility, and good electrical conduction properties. Alternatively, Shadduck'419 teaches electrodes made of titanium, as titanium is a suitable conductive material which is adapted to deliver RF

energy to soft tissue of the esophageal lumen without ablating and necrosing surface tissue to a significant degree (column 9, lines 57-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Friedman'167 with the titanium electrodes as taught by Shadduck'419 to provide Friedman'167 with the same advantage of stimulating the esophageal lumen without ablating and necrosing the tissue.

Response to Arguments

6. Applicant's arguments with respect to claims 1-5; 7, 8, 10-15 and 17-23 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant argues that Friedman'167 teaches 360-degree annular electrodes, and that the electrodes are clamped around the sheath rather than contained included within. It is noted that nothing within the Figures or cited paragraphs suggests 360-degree annular electrodes. Fig. 5 clearly shows the electrodes to have a C-shape with an opening and therefore does not define a 360-degree annular construction. Furthermore, in order for the electrodes to be clamped over the probe structure, they must necessarily not comprise a 360-degree annular configuration, or they would not be able to be clamped securely given the resultant deformation of a fully ring-like structure when clamped. Additionally, it is reasonable to interpret the electrode structure being clamped to the sheath as being included with the sheath. Alternatively, the electrical contacts are clearly disclosed as being corporeally included within the sheath structure, and comprise conductive metal and therefore are capable of function as electrode

structures. Given this interpretation, the electrodes are clearly non-annular and clearly are included with or within the sheath structure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status Information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
15 September 2007

/George Manuel/
Primary Examiner